

**UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF DELAWARE**

ABBOTT LABORATORIES, an Illinois  
corporation,

Plaintiff,

v.

BANNER PHARMACAPS INC., a Delaware  
corporation,

Defendant.

Civil Action No. 07-CV-00754-GMS

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**ABBOTT'S REPLY TO BANNER'S FIRST COUNTERCLAIM**

Plaintiff, Abbott Laboratories ("Abbott"), hereby responds to the first counterclaim of defendant Banner Pharmacaps Inc. ("Banner"), as follows:

**THE PARTIES**

1. Upon information and belief and as pled by Abbott, Abbott is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois 60064.

**RESPONSE:** Admitted.

2. Banner is a corporation organized under the laws of the State of Delaware, having its principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, NC 27265.

**RESPONSE:** Admitted.

**JURISDICTION AND VENUE**

3. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the common law.

**RESPONSE:** The allegations in paragraph 3 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that Banner's first counterclaim purports to state a cause of action arising under some or all of the various statutes

cited in paragraph 3, but denies that this counterclaim has any merit. Abbott has moved to dismiss Banner's second counterclaim, and therefore makes no response to any allegation in this paragraph pertaining to that counterclaim.

4. This Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331, and 1338(a) and (b).

**RESPONSE:** The allegations in paragraph 4 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that this Court has subject-matter jurisdiction over Banner's first counterclaim, but denies that this counterclaim has any merit. Abbott has moved to dismiss Banner's second counterclaim, and therefore makes no response to any allegation in this paragraph pertaining to that counterclaim.

5. This Court has personal jurisdiction over Abbott because Abbott has availed itself of the rights and privileges of this forum by suing Banner in this judicial district and because Abbott conducts substantial business in, and has regular and systematic contacts with, this judicial district.

**RESPONSE:** The allegations in paragraph 5 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that it is subject to personal jurisdiction in this judicial district for purposes of the above-captioned litigation, but denies that Banner's first counterclaim has any merit. Abbott denies all remaining allegations in this paragraph. Abbott has moved to dismiss Banner's second counterclaim, and therefore makes no response to any allegation in this paragraph pertaining to that counterclaim.

6. Venue for these Counterclaims is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and § 1400(b).

**RESPONSE:** The allegations in paragraph 6 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that this district is a proper district to adjudicate Banner's first counterclaim, but denies that this counterclaim has any

merit. Abbott has moved to dismiss Banner's second counterclaim, and therefore makes no response to any allegation in this paragraph pertaining to that counterclaim.

**COUNTERCLAIM I: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '731 AND '326 PATENTS**

7. On information and belief, Abbott is the holder of approved new drug application ("NDA") No. 18-723 granted by the Federal Food and Drug Administration ("FDA") for Depakote® (divalproex sodium) delayed release tablets, indicated for treatment of epileptic seizures ("Abbott's product").

**RESPONSE:** Admitted, except that Abbott denies that the product described in NDA No. 18-723 is indicated solely for the treatment of epileptic seizures.

8. On information and belief, Abbott is the owner of U.S. Patent No. 4,988,731 ("the '731 patent") and U.S. Patent No. 5,212,326 ("the '326 patent"). Abbott has submitted these patents for listing with FDA, asserting that they claim Abbott's product.

**RESPONSE:** Abbott admits that it is the owner of the '731 patent and the '326 patent. Abbott further admits that NDA applicants are required to comply with 21 U.S.C. § 355(b)(1)(G), which states:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Abbott also admits that the FDA compiles a reference book entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," which lists any patent reported under § 355(b)(1)(G) to the FDA. Further answering, Abbott admits that, in compliance with 21 U.S.C. § 355(b)(1)(G) and in conjunction with the filing of NDA No. 18-723, Abbott informed the FDA of the existence of the '731 patent and the '326 patent and further informed the FDA that these two patents cover the compound divalproex sodium. Finally, Abbott admits that the claims of the '731 patent and the '326 patent have been interpreted by the

United States Court of Appeals for the Federal Circuit, which has ruled that those patents are valid and enforceable and that they cover divalproex sodium. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002).

9. Banner has submitted § 505(b)(2) new drug application 21-152 (“Banner’s NDA”) to FDA for regulatory approval to sell valproic acid delayed release capsules, also for treating epileptic seizures (“Banner’s product”). Valproic acid is a chemical entity related to divalproex sodium. FDA advised Banner to rely on Abbott’s product as the reference listed drug for Banner’s product.

**RESPONSE:** On information and belief, Abbott admits that Banner has submitted Banner’s NDA to the FDA and that Banner has – at times – characterized the product described therein as a valproic acid delayed-release capsule to be used in treating epileptic seizures. Rather than claim a valproic acid product as the reference-listed drug for its product, however, Banner claims that the proper reference-listed drug for its NDA is Depakote®, which has divalproex sodium as the active ingredient. Abbott further admits that valproic acid and divalproex sodium share an active moiety, but denies that they are the same compound or are otherwise chemically identical; to the contrary, FDA recognizes valproic acid and divalproex sodium as distinct chemical entities. Abbott lacks sufficient information to admit or deny Banner’s claim that the FDA advised Banner to refer to Abbott’s Depakote® product as the reference-listed drug for Banner’s product, and therefore denies this allegation. Abbott denies all remaining allegations in this paragraph.

10. In its NDA, Banner submitted a “Paragraph IV” certification that Banner’s product does not infringe the ‘731 patent or the ‘326 patent.

**RESPONSE:** On information and belief, Abbott admits that, in Banner’s NDA, Banner submitted a certification under 21 U.S.C. § 355(b)(2)(iv) of the Federal Food, Drug, and Cosmetic Act asserting that the Banner NDA product would not infringe the ‘731 patent or the

'326 patent, and sought FDA approval to market the Banner NDA product before the '731 patent and the '326 patents expire. Abbott denies all remaining allegations in this paragraph.

11. The '731 patent is not infringed by Banner's product because of the requirement in all claims of the patent for an oligomer having a 1:1 molar ratio of sodium valproate and valproate acid. Banner's product does not contain an oligomer of sodium valproate and valproic acid. Banner's product contains only valproic acid. For this reason, Banner's product does not infringe, either literally or under the doctrine of equivalents, the '731 patent.

**RESPONSE:** The first and fourth sentences of paragraph 11 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott denies that Banner's product does not infringe the '731 patent. Further responding, and on information and belief, Abbott denies the allegations of the second and third sentences of paragraph 11 because Banner has represented to FDA and Abbott that the appropriate reference-listed drug for Banner's NDA product is Depakote® (which has divalproex sodium as the active ingredient), not one of the many FDA-approved products containing valproic acid as the active ingredient. Abbott denies all remaining allegations in this paragraph.

12. The '326 patent is not infringed by Banner's product because of the requirement in all claims of this patent, as well, for an oligomer having a 1:1 molar ratio of sodium valproate and valproate acid. Banner's product does not contain an oligomer of sodium valproate and valproic acid. Banner's product contains only valproic acid. For the same reason, Banner's product does not infringe the '326 patent, either literally or under the doctrine of equivalents.

**RESPONSE:** The first and fourth sentences of paragraph 12 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott denies that Banner's product does not infringe the '326 patent. Further responding, and on information and belief, Abbott denies the allegations of the second and third sentences of paragraph 12 because Banner has represented to FDA and Abbott that the appropriate reference-listed drug for Banner's NDA product is Depakote® (which has divalproex sodium as the active ingredient), not one of the many FDA-approved products containing valproic acid as the active ingredient. Abbott denies all remaining allegations in this paragraph.

13. Abbott has commenced this action against Banner, alleging that Banner's NDA containing the aforesaid Paragraph certification is an act of infringement concerning the '731 patent and the '326 patent.

**RESPONSE:** Admitted.

14. There is an actual, substantial, and justiciable controversy between Banner and Abbott regarding infringement of the '731 patent and the '326 patent.

**RESPONSE:** The allegations contained in paragraph 14 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that this Court has subject-matter jurisdiction to adjudicate Banner's counterclaim, but denies that Banner's counterclaim has any merit.

15. Banner is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of the Banner product has not infringed, does not infringe, and will not infringe the '731 patent or the '326 patent, either directly or under the doctrine of equivalents.

**RESPONSE:** Denied.

#### **COUNTERCLAIM II: UNFAIR COMPETITION**

At this time, Abbott does not respond to the allegations contained in paragraphs 16 through 20 of Banner's counterclaims. Under separate cover, Abbott has moved to dismiss Banner's second counterclaim alleging unfair competition.

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Abbott denies all allegations contained in paragraphs 1-15 that are not specifically admitted above.

**RELIEF**

Abbott respectfully prays that this Court (i) deny Banner any relief; and (ii) award Abbott any further such relief as the Court deems just and appropriate.

Dated: February 20, 2008

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that, on February 20, 2008, a true and correct copy of the foregoing document, entitled **Abbott's Reply to Banner's First Counterclaim**, was caused to be served on the following via CM/ECF filing and the following methods:

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